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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,891	06/02/2000	ROGER C. LEVESQUE	9555.96USWO	3581

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GOUDREAU GAGE DUBUC
800 PLACE VICTORIA, SUITE 3400
MONTREAL, QUEBEC, H4Z 1E9
CANADA

EXAMINER	
SISSON, BRADLEY L	
ART UNIT	PAPER NUMBER
1634	19

DATE MAILED: 06/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/508,891	LEVESQUE ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *1-3 and 13-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Location of Application

1. The location of the subject application has changed. The subject application is now located in Group 1630, Art Unit 1634, and has been assigned to Primary Examiner Bradley L. Sisson.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 4-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *In re Wands*, 8 USPQ2d 1400 (CAFC 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Quantity of Experimentation Necessary

The quantity of experimentation need is great, on the order of several man-years and then with little, if any, reasonable expectation of success.

The Amount of Direction or Guidance Provided

The guidance provided by the specification is limited to specific genes of a single species of bacteria and then the "selective condition" is not readily apparent.

The Presence or Absence of Working Examples

The specification provides but two examples:

Example 1, pages 26-27, EGT assay using two primer pairs on two *Pseudomonas aeruginosa* genes; and

Example 2, pages 27-31, Validation of the EGT assay using *Pseudomonas aeruginosa* genes.

Upon review of Example 1, it appears that the "selective condition" employed was the inclusion of kanamycin in the culture media. However, the cells demonstrated resistance to kanamycin even after having undergone mutagenesis. Accordingly, the "selective condition" did not select for one group of cells over that of another.

A review of the disclosure fails to find adequate guidance for the analysis of any other type of cell, e.g., be it from any animal, be it invertebrate, chordate, mammalian, including human, or from any plant has been disclosed. Accordingly, the failure of the specification to enable the full scope of the claims unfairly shifts the burden of enablement from applicant to the public. The

situation at hand is analogous to that in *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001. As set forth in the decision of the Court:

> " '[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.' *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) ('[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.').
>
> *****
>
> "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (starting, in context of the utility requirement, that 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.') Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.
> "It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. <u>However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art.</u> It is the specification, not the knowledge of one skill in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research. (Emphasis added)

While the instant application does provide limited guidance, as indicated above, the shallowness of the disclosure at best provides only an invitation for others to develop the starting materials

and reaction conditions that would enable the practicing of the claimed method for the full breadth of the claims' scope.

The Nature of the Invention

The claimed invention relates directly to matters of physiology and chemistry, which are inherently unpredictable and as such, require greater levels of enablement. As noted in *In re Fisher* 166 USPQ 18 (CCPA, 1970):

> In cases involving predictable factors, such as that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.

The State of the Prior Art

The state of the prior art has developed to the point where it recognizes that predicting properties and utilities of expressed modified proteins is quite unpredictable. With the claimed method ultimately having utility in the properties of the expressed proteins, one needs to have some capacity to predict the outcome of such experiments. The claimed method, however, provides no such assurance. The claimed invention relates directly to matters of physiology and chemistry, which are inherently unpredictable and as such, require greater levels of enablement. *Ibid.*

The Relative Skill of Those in the Art

The relative skill of those in the art that is most closely associated with the claimed invention is high, on par with those that hold a Ph.D. in biochemistry.

The Breadth of Scope of the Claims

The claims have sufficient breadth of scope so to encompass the analysis of every region of every gene of every organism and that said functional analysis could be performed under every possible "selective condition."

In view of the breadth of scope clamed, the limited guidance provided, the unpredictable nature of the art to which the claimed invention is directed, and in the absence of convincing evidence to the contrary, the claims have not been found to be enabled by the disclosure.

Response to argument

4. At page 3 of the response received 06 March 2002 it is asserted that one of skill in the art could practice the full scope of the invention without having to resort to research and development over several years, yet no evidence is provided refuting the assertion of the Office. Further, applicant asserts that the claimed invention can be practiced "using known, reproducible and reliable techniques." This argument has been fully considered and has not been found persuasive, as the claims are not limited to where one is to only utilize such "reproducible and reliable techniques." It is noted with particularity that limitations found within the specification are not read into the claims, but rather, the claims are read as broadly as is reasonably possible.

Even if the claimed method were to be further limited to the use of certain "known, reproducible and reliable techniques," the specification does not provide adequate guidance as to how these techniques are to be modified and adapted so to enable the non-obvious method.

5. At page 3, applicant directs attention to examples found at page 26-29 where *Pseudomonas aeruginosa* was used to exemplify the claimed invention. Such guidance, however, has not been found sufficient to enable the full scope of the claimed invention. It is noted with particularity that the claimed invention is not limited to the analysis of prokaryotes, which are recognized as lacking intronic sequences. In comparison, the claimed method encompasses mammalian genomic nucleic acids, which most certainly do comprise introns. While the method was used to confirm a positive in that eight known genes were used, the claimed method encompasses the identification of essential genes when the genes themselves are not necessarily known. Accordingly, the specification has not set forth in sufficient detail how the claimed invention is to be practiced with any and all sources of genetic material.

6. At page 5 it is asserted that the claimed method has nothing to do with predicting properties of proteins. This argument, however, has not been found persuasive for as seen in claim 11, one is looking for resistance to cytotoxic agents. Clearly, resistance is manifest in the protein so encoded.

7. At page 5, bridging to page 6, it is asserted that the claimed method is directed to an "EDT assay" (Essential Gene Test assay) that "can be adapted to any viral, bacterial, fungal or eukaryotic cell that has haploid genome or known sequences available in databases for prior synthesis and by screening by PCR and/or other methods for nucleic acid amplification." Also

asserted is that the Office has not set forth evidence that would fairly question the enablement provided.

8. The above argument has been fully considered and has not been found persuasive towards the withdrawal of the rejection. While agreement is seemingly reached in that the claimed method can be adapted so to enable the detection/identification of various essential genes, the level of skill required so to enable one of skill in the art to fully practice the claimed invention has been found to rise to the level of undue experimentation. In support of this position, it is noted that the no evidence has been presented that refutes the position that the amount of time required so to enable the practicing of the full scope of the invention would be on the order of several years, if it can every be fully enabled. While applicant has asserted that the claimed invention is directed to an area of technology labeled as "biotechnology," such is still considered to fall foursquare within the chemical arts, as is supported by the classification systems used by the USPTO in classifying patents drawn to genes and assays. Accordingly, the very subject matter is considered to be highly unpredictable and deserving of greater levels of disclosure. While agreement is reached in that there is no per se rule that applicant must provide an example in order to satisfy the enablement and written description requirements of 35 USC 112, first paragraph, attention is directed to the decision in *In re Shokal* 113 USPQ 283 where it was held that exemplification of a single species can rarely support a claim to a genus.

Claim Rejections - 35 USC § 101

9. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 4-12 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and credible asserted utility or a well-established utility.

11. The claimed method is drawn to the analysis of sequence tags. The tags are not derived from any known gene nor are they known to have any specific and useful property, nor does the claimed method result in he identification of specific and useful sequences

12. Claims 4-12 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Response to arguments

13. Argument is advanced at page 6 of the response where it is asserted that the claimed invention will result in the identification of essential genes of an organism. It is further asserted that these genes can be the subject of research but may also yield important information, citing various examples. This argument has been fully considered and has not been found persuasive, as the claims are not restricted to the identification of essential genes that have any particular utility. The generation of information in and of its self does not necessarily convey patentable utility. It matters not whether the claim is drawn to a product or process; the claim must be drawn to an invention that satisfies the utility requirements as set forth under 35 USC 101 and as further developed in the Utility Guidelines. In support of this position, attention is directed to *Brenner, Comr. Pats. v. Manso*n, 148 USPQ 689 (US SupCt 1966):

> Whatever weight is attached to the value of encouraging disclosure and of inhibiting secrecy, we believe a more compelling consideration is that a process patent in the chemical field, which has not been developed and pointed to the degree of specific

> utility, creates a monopoly of knowledge which should be granted only if clearly commanded by the statute. Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development, 22 without compensating benefit to the public. The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.
>
> * * *
>
> We find absolutely no warrant for the proposition that although Congress intended that no patent be granted on a chemical compound whose sole "utility" consists of its potential role as an object of use-testing, a different set of rules was meant to apply to the process which yielded the unpatentable product. 24 That proposition seems to us little more than an attempt to evade the impact of the rules which concededly govern patentability of the product itself.
> This is not to say that we mean to disparage the importance of contributions to the fund of scientific information short of the invention of something "useful," or that we are blind to the prospect that what now seems without "use" may tomorrow command the grateful attention of the public. But a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.

For the above reasons, and in the absence of convincing evidence to the contrary, the rejection is maintained.

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

15. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (703) 308-3978. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

18. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

B. L. Sisson

Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
June 3, 2002